

Appl. No. 09/945,225

Response AF dated April 27, 2004

Reply to Final Office Action of January 28, 2004

REMARKS

Applicants have carefully reviewed the Final Office Action mailed January 28, 2004. Claims 1-21 are pending and were rejected. Applicants thank the Examiner and his supervisor Brian Casler for granting telephone interviews.

Claim Rejections—35 U.S.C. § 102

Claim 1 was rejected under 35 U.S.C. § 102(e) as being anticipated by Samson et al. (U.S. Patent No. 6,090,099). Applicants respectfully traverse the rejection.

In re Hack, 114 USPQ 161, is cited in support of the Examiner's interpretation of "shapeable" as a product-by-process limitation. The Examiner's reasons for citing this case are not clear because the case does not involve product-by-process claims or assertions. *In re Hack* discusses new uses for old products, stating that patentability of a composition or machine cannot be predicated on a new use, and that only process or method claims can protect a new use. In *Hack*, the product was asserted as being patentable based on an intended use. In the present case, the claims are directed to a product with specific structural features that are not found in the cited prior art. No intended use is claimed or relied on for distinguishing the claimed invention from the prior art.

The Examiner also cites *In re Thorpe, et al.* However, the facts of *Thorpe* are quite different from the instant case. The applicant in *Thorpe* did not assert the product of its process was different from the product of the prior art, and merely argued that because the process was patentable, the resulting product should be, too. The court re-asserted the standard rule that while process claims may be allowable, the product in a product-by-process claim must be allowable based on distinguishing characteristics. The facts of the instant situation are quite

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different. In the instant case, Applicants do assert that their product differs structurally from the product of the prior art. Additionally, while the claims at issue in *Thorpe*, stated "product of the process of claim 1" and were thus clearly product-by-process claims, the instant claims are straight product claims, without any reference to the process by which the product is produced. The Examiner's assertion that the claims are product-by-process is contrary to the language of the claims.

The Examiner also cites *In re May, et al.* However, the facts of *May* are also quite different from the instant case. In *May*, the Applicant claimed a new use for a known drug product. The issues related to whether the effect of the drug was unexpected, not to any structural differences in products or assertions of product-by-process claims.

The Examiner states that he is interpreting the instant product claims as product-by-process claims. However, the Examiner has given no reasoning to support this interpretation. The instant claims are directed to a product and recite the structure and characteristics of that product. The claims do not recite method steps. The phrase "having a shapable length that is shapable by thermoforming techniques" further limits the recited structure, "distal tip". The claims do not recite a tip that is shaped, or a step of shaping the tip, which would be product-by-process limitations. Instead, the claims recite a tip that is shapable. This is a structural limitation entitled to full patentable weight. The dictionary definition of "shapable" is "capable of being shaped", as shown in the attached page from the Merriam-Webster Online Dictionary. Applicant submits that the phrase "capable of" is commonly used to further describe structures in product claims, without transforming the product claims into product-by-process claims. The limitation that the tip is "shapable" means that it can be shaped, but is not necessarily shaped. This limitation describes a structural characteristic of the product, not a process step. No active

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action, process or method is inferred by the term "shapable". The adjective "shapable" modifies the noun "tip," thus further limiting the claimed structural feature (the tip of the catheter).

Additionally, the Examiner's basis for interpreting "thermoforming techniques" as a method of manufacturing the catheter is not clear. Process claims require positive method steps to be performed, and are generally recited using the -ing or -ed form of verbs. For example, a process step could be "shaping the distal tip of the catheter" or "the distal tip is shaped." These phrases indicate some action has been done, i.e., some process has been performed. The instant claims do not recite any positive process steps and do not recite any limitations regarding how the product is manufactured. What the product claim does recite is specific features and characteristics of the product. Applicants submit a product claim reciting a structural element that is capable of being manipulated in some way or is capable of doing something does not transform the product claim into a product-by-process claim.

In response to Applicants previous arguments regarding the structural differences between Samson et al. and the instant claims, the Examiner merely states that the prior art teaches the claimed invention, without providing further explanation or indications where in Samson et al. the claimed structures are discussed. As this is an anticipation rejection, the cited reference must teach each and every limitation of the rejected claim. The Examiner's only reference to Samson et al. regarding a teaching of a shapable tip is Figures 1 and 2. However, there is no indication in the figures that the tip of the catheter of Samson et al. has a structure that is shapable. The catheter of claim 1 has a distal tip that may be given a shape, such as a bend, after it has been manufactured. For example, a doctor may be able to shape the tip of the catheter into a desired configuration for a particular patient's vasculature. Samson et al. disclose no equivalent structure.

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Additionally, Samson et al. fail to teach the limitation recited in claim 1 that the second layer has a first segment extending to a distal terminus and a second segment extending from the distal terminus to a radiopaque marker band disposed proximal of the distal end of the shaft. This claimed embodiment is illustrated in Figure 4. The Examiner's only discussion of a second layer is the assertion that Figure 2 of Samson et al. shows a second layer disposed at the inner liner between the distal terminus and the distal end of the shaft. However, the second segment of the second layer of Samson et al. (reference 202) extends beyond the marker (reference 212). Thus, Samson et al. fails to teach each and every limitation of the claim, and cannot be seen to be anticipatory. Withdrawal of the rejection is respectfully requested.

Claim Rejections—35 U.S.C. § 103

Claims 1-5, 7-10, 12 and 13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Samson et al. Additionally, claims 1-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Samson et al. as applied above and further in view of Nita et al. (U.S. Patent No. 5,951,539). Applicants respectfully traverse these rejections.

As discussed above in detail, Samson et al. fail to disclose the elements of a distal tip having a shapeable length that is shapeable by thermoforming techniques, and a second segment of a second layer extending from the distal terminus to a radiopaque marker. Likewise, Nita et al. do not disclose these elements. These elements are required by the two independent claims, claims 1, and 14. As the prior art, alone or in combination, does not disclose each and every element of the inventions of these claims, Applicants submit that these claims are in condition for allowance. As claims 2-13 and 15-21 depend from claims 1 and 14, respectively, and contain additional elements, Applicants submit that these claims are also in condition for allowance.

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Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

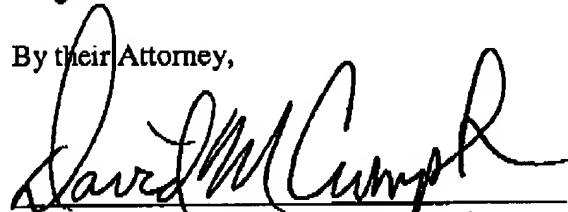
Respectfully submitted,

Ting Tina Ye et al.

By their Attorney,

Date: _____

4/27/04



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Attachment: One (1) Merriam-Webster Online Dictionary page.

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Merriam-Webster Online Dictionary

One entry found for shapable.

Main Entry: **shap·able** 1)

Variant(s): **or shape·able** 1) /'shA-p&-b&l/

Function: *adjective*

1 : capable of being shaped

2 : SHAPELY

Get the Top 10 Search Results for "shapable"

For More Information on "shapable" go to Britannica.com

Pronunciation Symbols

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